DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 6 2004

Ms. Lorna Gamboa
Regulatory Affairs Manager
Varian, Inc.
Consumable Products
25200 Commercentre Drive
Lake Forest, CA 92630

Re: k033659
Trade/Device Name: OnTrak Test Tcup® and OnTrak Test Tstik®
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, DIO, DJG, LDJ, LCM, LDJ, JXM, DIS
Dated: November 19, 2003
Received: November 21, 2003

Dear Ms. Gamboa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K033659

Device Name: OnTrak TesTcup and OnTrak TesTstik

Indications for Use:

OnTrak TesTcup and OnTrak TesTstik products, as listed below, are in vitro diagnostics tests intended for professional use for the qualitative detection of drugs in urine at or above the stated cutoff concentrations.

OnTrak TesTcup Products:
OnTrak TesTcup 4
OnTrak TesTcup 5
OnTrak TesTcup 5 M2K
OnTrak TesTcup 501
OnTrak TesTcup PRO-5

OnTrak TesTstik Products:
OnTrak TesTstik AMP
OnTrak TesTstik BAR
OnTrak TesTstik BNZ
OnTrak TesTstik COC
OnTrak TesTstik MET
OnTrak TesTstik MOR
OnTrak TesTstik PCP
OnTrak TesTstik THC
OnTrak TesTstik 2 COC/THC
OnTrak TesTstik 3 COC/MOR/THC

Cutoff Concentrations:

Amphetamines	1000 ng/mL	Morphine	300 ng/mL
Barbiturates	200 ng/mL	Morphine (M2K)	2000 ng/mL
Benzodiazepines	100 ng/mL	Phencyclidine (PCP)	25 ng/mL
Cocaine metabolite	300 ng/mL	Tetrahydrocannabinols (THC)	50 ng/mL
Methamphetamine	500 ng/mL		

OnTrak TesTcup and OnTrak TesTstik products provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033659

Prescription Use ✓ OR Over-the Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)